

15. A surgical stapler comprising:

- a. a disposable staple cartridge, wherein said disposable staple cartridge having a staple feeding mechanism, wherein said staple feeding mechanism having a rail to guide staples contained within said disposable staple cartridge, and wherein said staple feeding mechanism having a window opening in a housing tower which engages a forming tool;
- b. a handle assembly, wherein said handle assembly having a staple forming mechanism utilizing a forming tool to lock said disposable staple cartridge into said handle assembly, and wherein said handle assembly having a pivot screw to connect said handle assembly with an actuating trigger;
- c. an actuating trigger, wherein said actuating trigger is pivotally connected in combination to said staple forming mechanism and said staple feeding mechanism secured in a frame, and wherein said actuating trigger is designed to

operate in three main positions:

- (i) a fully opened position, wherein said disposable staple cartridge is disengaged from a forming tool and can be removed and replaced by a new one;
- (ii) a ready to use position, wherein gear teeth of said actuating trigger forces said forming tool to slide between guides inside walls of said handle assembly, wherein a rack and pinion action between said teeth of said actuating trigger and teeth of said forming tool guarantees a very precise and smooth motion of said forming tool inside said guides and said window opening in said housing tower of said disposable staple cartridge, wherein snap features of a trigger release assembly snap into a housing lip of said handle assembly, and wherein said forming tool engages into said window opening of said disposable staple cartridge

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and aligns and locks said disposable staple cartridge into position completely aligning said forming tool to a centerline of a staple ready to be formed preventing jamming of said staple during closing of a wound or incision;

- (iii) a fully closed position, wherein a top surface of said actuating trigger hits inside top of said handle assembly, wherein said gear teeth of said actuating trigger forces said forming tool downward to make contact with a top section of a staple so that extension legs of said forming tool start the deformation of said legs, wherein a mid-section of said staple is resisted by an anvil continuing until an edge of said forming tool has completely reached bottom and presses against said top section of said staple, wherein said forming tool has completely finished a downward path of side legs of said staple,

wherein said staple clears lips of said disposable staple cartridge, and wherein said staple is free to clear said disposable staple cartridge to be implanted in a wound or incision;

- d. a trigger release mechanism, wherein said actuating trigger release mechanism having a leaf spring, wherein said actuating trigger release mechanism having two latches with two release buttons and two snap features, made out of a resilient plastic which are heat staked or ultrasonically welded to said leaf spring, wherein said trigger release mechanism allows engagement and disengagement of said actuating trigger with said handle housing, wherein pressing-in on said release buttons allows said snap features to disengage with a lip on said handle assembly housing allowing said actuating trigger to fully open permitting the discharge of an empty disposable cartridge, wherein said snap features when engaged with a lip on said handle assembly housing prevents said actuating trigger from fully opening in said ready to use position; and wherein said snap features during said closing motion do not restrict movement of said actuating trigger.

16. A surgical stapler comprising:

- a. a disposable stapler cartridge, wherein said disposable staple cartridge is an assembly comprising:
 - (i) staples;
 - (ii) a rail, wherein said rail is a high strength steel plate formed to provide a surface for said staples to ride on;
 - (iii) an anvil formed at the front of said rail to provide support to said staple during a forming operation;
 - (4i) large holes on bottom surface of said rail to provide user a passive visual indication of the number of staples in said disposable staple cartridge;
 - (5i) a cartridge housing made out of a resilient plastic material assembled to said rail by heat staking or ultrasonically welding cartridge pins to holes located on both side surfaces of said rail;
 - (6i) a coil spring retained inside a cylindrical cavity of said cartridge housing allowing said coil spring to extend only in a longitudinal direction of said disposable cartridge assembly;
 - (7i) two lips built-in said cartridge housing for retaining said staple at the front in place and ready to be formed;

- (8i) an end cap made out of resilient plastic material and assembled to said rail via two snaps located at the bottom of said cap, wherein said end cap surfaces slide under the bottom surface of said cartridge housing;
 - (9i) a pusher to provide a constant force against said staples via a compression force exerted by said coil spring;
 - (10i) two cantilever snaps at the back end of said cartridge housing providing a means of engagement to said handle housing when said disposable staple cartridge is loaded into said surgical stapler;
 - (11i) a tower at the front end of said cartridge housing with a window opening that provides access to a forming mechanism once an actuating trigger is rotated to a ready-to-use position, and wherein said forming mechanism is in perfect alignment with said staple.
- b. a handle assembly with a pivot screw;
 - c. an actuating trigger, wherein said actuating trigger is operable in three distinct positions;
 - d. a trigger release mechanism.

REMARKS – General

By the above amendment, Applicants have amended the **Abstract** to a **narrative form** and removed

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legal phraseology. The amended Abstract now describes the disclosure sufficiently so that a reader is assisted in deciding whether there is a need for consulting the full patent text for details.

Also, applicants have rewritten all **claims** to define the invention more particularly and distinctly so as to overcome the technical rejections and define the invention over the prior art.

The objection to The Specification And The Claims Rejection Under M.P.E.P. 609.04(a), M.P.E.P. 608.01(b), M.P.E.P. 608.01(m)[R-3], 35 U.S.C. 112, and 35 U.S.C. 103.

Concerning telephone interview conducted with Examiner Nash on 2006 Jan. 11, applicant discussed changes made to the Abstract and Claims which applicant faxed to the Examiner, at his personal fax number 571-273-4465, prior to the interview.

Examiner read the Abstract and said that the Abstract was allowable with the exception of a minor change. That change being changing a "the" to an "a" in front of disposable staple cartridge. Applicants made the change, and that change is amended in the Abstract submitted above.

Examiner said that the Claims applicant submitted would cause him to conduct a new search. Examiner explained that he was not looking for the applicants to rewrite new claims – but, to combine, reorganize, and place in proper form the original claims. Examiner said that applicants should combine Claim 1, as a base claim, with Claim 4, and combine Claim 1 with Claims 6 or 11. Applicant asked Examiner if the combination of Claim 1 with Claim 6 or 11 should be a dependent Claim. Examiner responded that the combination of Claim 1 with Claim 6 or Claim 11 should be an independent claim.

Applicants made the changes with respect to combining Claim 1 with Claim 4 and combining Claim 1 with Claim 6. The Claims submitted above show this combination, and applicants have placed the claims in proper organization and form.

Applicant discussed with the Examiner his objection to references being cited in the specification, and applicant asked the Examiner if he should rewrite the specification and remove those references. The Examiner responded that "no" it was not necessary to rewrite the specification, and he further responded that for those references to be considered pertinent they would have had to have been submitted on Form 1449. And, Examiner stated that those references would not be considered – but, that it was not necessary for applicant to rewrite the specification.

Concerning the Office Action mailed 2005 Dec. 21, on page 5 number 7 the Examiner rejects Claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over US 4,109,844 to Becht – Insofar as the claimed invention is understood. The major difference between Becht's invention and the Applicants is: Becht's invention is primarily for a "single use, disposable stapler". The Applicant's invention is a surgical stapler with a "disposable staple cartridge". The Examiner has misunderstood the reference. The reference does not teach what the Examiner relies upon it supposedly teaching, and the Examiner has made a strained interpretation of the reference. The Examiner admits in the second paragraph on page 5 number 7 that Becht does not explicitly disclose that the surgical stapler has a disposable staple cartridge.

Becht does not "explicitly disclose that his surgical stapler has a disposable staple cartridge" because there is "no" staple cartridge. In fact, he states that there is no staple cartridge or magazine in his

stapler. Becht states in the last paragraph in his Description of the Prior Art:

"No force is required on the part of the operator to shift a staple from a cartridge or magazine to the anvil about which it is formed. In addition, bending of the crown of the staple during the forming step is controlled. The surgical stapling instrument will hold more staples than those requiring a staple cartridge."

That is "why" Becht is stating that his stapler is superior to prior art - because staplers found in the prior art with cartridges or magazines require upwards of 20 pounds of force to form and implant the staple.

Becht mentions that his stapler may be manufactured as a non-disposable stapler enabling the replacing of various parts such as an additional supply of staples. However, Becht teaches that covers 63 and 47 of nose portion should be affixed with screws or the like so that they can be removed so that various parts can be replaced/repared. And, these covers can be removed for additional staples to be added. The removal of a cover on the nose portion of Becht's stapler for the addition of staples is simply that...by no stretch of the imagination a disposable staple cartridge. It is apparent, even more so, that Becht's stapler is intended as a single use disposable stapler due to the fact that Becht does not bother to point out which cover 63 or 47 should be removed to add more staples to the stapler. And, since Becht has already concluded that his stapler is superior due to its

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design by no use of a cartridge or magazine - how can the examiner conclude that the replacing of additional staples on the anvil be the exact same, (i.e., a disposable cartridge), as the present invention? It simply is not the same.

It is obvious only to the examiner, after reviewing the present invention, that choosing the forming tool to lock a disposable/removable staple cartridge in place is the best location. However, since Becht's invention uses no staple cartridge it was not an obvious choice or even a consideration because it was not pertinent to his invention.

The Examiner should consider the following reasons as to "why" Becht's stapler does not have a removable staple cartridge:

1.) Becht's stapler is intended to be a single use, disposable stapler. The Examiner has made a strained interpretation in concluding that the nose of Becht's stapler is a disposable cartridge. For example: If a surgeon is using Becht's stapler in a single use, disposable form and he has emptied the stapler of staples. Do you think he would bother to pull out the nose section and replace it with another "new" nose section full of staples taking the chance, that the new nose section might not fit as well in the old disposable handle house and disposable actuating trigger, that it could misfire? Would it not be prudent on the part of the surgeon using Becht's stapler to just replace the emptied

stapler with a brand new stapler? It wouldn't make any sense for the surgeon to replace a new nose section in a handle section and actuating trigger section, which too are intended for a single use. Becht does not teach that his handle section or actuating section, in a disposable form, are constructed out of a sturdier plastic than the nose section, and Becht does not teach that in the disposable form the handle housing and actuating trigger are intended to be used over and over for more than a single use.

2.) If Becht's stapler was manufactured in a non-disposable form, does the Examiner feel that a surgeon, during the course of a surgical procedure with a patient lying on the table, would take the time to remove covers 63 or 47 to replace parts or staples? A surgeon would not do this. Nor, would a surgeon remove the nose section of Becht's stapler and replace it with another nose section due to the fact of the possibility of a malfunction or misfire.

The Examiner, also, is making a strained interpretation when he concludes that because parts of Becht's stapler are detachable from each other that this is same thing as being a removable, disposable staple cartridge.

In the Office Action the Examiner has concluded that Applicant's **Claims 4-14** are **Allowable Subject Matter**.

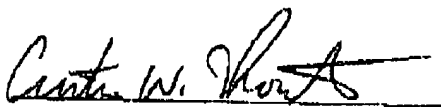
Conclusion

For all the above reasons, applicants submit that the specification and claims are now in proper form, and that the claims all define patentably over the prior art. Therefore they submit that this application is now in condition for allowance, which action they respectfully solicit.

Conditional Request for Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If for any reason this application are not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. 706.03(d) and 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully,



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Date: Jan 24 2006



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Date: Jan 24 2006

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Recordation Date: November 09, 2005
700207959A